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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,474	04/18/2001	Sau-Hung S. Leung	845.27,700	9942
29668	7590	11/03/2004	EXAMINER	
PFIZER, INC. 201 TABOR ROAD MORRIS PLAINS, NJ 07950			SHEIKH, HUMERA N	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,474

Applicant(s)

LEUNG ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of Amendment and Applicant's Arguments/Remarks filed 01/28/04 and 03/11/04 and the request for extension of time (1 month-granted) filed 03/11/04 is acknowledged.

The claim objection under 37 CFR §1.75(c) for claim 29 has been *withdrawn* in view of Applicant's amendment, canceling claim 29.

Claims 18-28 are pending. Claims 1-17 and 29 have been cancelled. Claims 18-28 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 18 and 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hijiya *et al.* (US Pat. No. 4,562,020) in view of Nair *et al.* (WO 98/11867).

Hijiya *et al.* ('020) teach strong, water-soluble films comprising pullulan. Hijiya *et al.* do not teach at least two oils.

Nair *et al.* ('867) teaches oral compositions comprising thymol, methyl salicylate, eucalyptol and menthol as flavoring and antibacterial agents. These oils may be used alone or in combination.

Art Unit: 1615

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine Hijiya *et al.* with Nair *et al.* and incorporate at least two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptol and menthol with the motivation of providing more flavor and antimicrobial properties to the film of Hijiya *et al.* The period of time necessary for mixing (*i.e.*, 2 to 48 hours as in instant claim 26) would have been obvious to one skilled in the art at the time of the invention with the motivation of ensuring homogeneous mixing of the formulation.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hijiya *et al.* (US Pat. No. 4,562,020) in view of Zerbe *et al.* (US Pat. No. 5,948,430) and further in view of Nair *et al.* (WO 98/11867).

Hijiya *et al.* ('020) and Nair *et al.* ('867) are relied upon for all that they teach as stated previously.

Zerbe *et al.* ('430) is relied upon for teaching the inclusion of surfactants in water-soluble film preparations.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to incorporate surfactants, as taught by Zerbe *et al.*, into the water-soluble film of Hijiya *et al.* ('020) with the motivation of increasing the wettability of the film.

Response to Arguments

Applicant's arguments filed 03/11/04 have been fully considered.

Firstly, Applicant argued regarding the claim objection under 37 CFR § 1.75(c) for Claim 29. Applicants have cancelled Claim 29 to obviate the claim objection. Accordingly, the claim objection for claim 29 has been withdrawn.

Secondly, Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 18-28 as being unpatentable over Hijiya et al. ('020) in view of either Nair *et al.* ('867) or Zerbe *et al.* ('430) either alone or in combination, stating, "Hijiya does not disclose a method comprising mixing oils to form an oil mixture comprising two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptil to provide pullulan films having antimicrobial properties."

This argument has been fully considered, but was not found to be persuasive. Hijiya *et al.* teach a process for a self-supporting film, whereby the film may be admixed with one or more ingredients that include fats, antibiotics, lecithin and the like (see col. 3, lines 27-34 & claim 10). Fats are oily substances that are not soluble in water. Antibiotics are further included to inhibit or kill the growth of microorganisms. Hijiya *et al.* also teach menthol as one of the suitable flavoring agents. Nair *et al.* is relied upon for the teaching of the obviousness of employing one or more essential oils, chosen from thymol, methyl salicylate, eucalyptol and menthol, and mixtures thereof as flavoring and antibacterial agents in oral breath freshening compositions (see pg. 15, lines 22-30). Since Hijiya *et al.* teach oils, such as menthol in pullulan compositions and Nair *et al.* further teach the inclusion of oils, such as menthol, thymol, eucalyptol, etc. in oral

Art Unit: 1615

compositions, whereby both references desire antimicrobial and antibacterial properties, a *prima facie* case of obviousness has been clearly established by the cited prior art.

Thirdly, Applicant argued, "Like Hijiya *et al.*, Zerbe *et al.* do not teach or suggest forming a mixture of oils containing at least two of thymol, methyl salicylate, eucalyptol and menthol to provide pullulan films having antimicrobial properties."

This argument has been fully considered, but was not found to be persuasive. The teachings of Hijiya *et al.* have been delineated above. The argument that 'Zerbe does not teach a mixture of oils' is not persuasive since Zerbe *et al.* was relied upon solely to remedy the deficiency of a *surfactant* in Hijiya *et al.* Zerbe *et al.* was not referenced upon to teach a mixture of oils, as Nair *et al.* has initially met and resolved this deficiency of Hijiya *et al.*, by explicitly teaching a mixture of oils, such as those instantly claimed. Zerbe *et al.* teach the use of surfactants in film-forming preparations (see col. 2, lines 50-64) and thus mitigate the deficiency of Hijiya *et al.*

Lastly, Applicant argued, "The methods of the present invention teach improving the antimicrobial effectiveness of essential oils in coral care products by incorporating at least two such oils in pullulan containing films. Nair is silent concerning the use of stand alone film technology."

This argument was not found persuasive. Nair *et al.* teach that the essential oils are used in amounts effective to provide antimicrobial activity in the oral cavity (pg. 15, lines 13-14). Nair *et al.* further teach suggestive amounts of each of the oils. At page 16, Nair *et al.* teach a mouthwash containing a zinc salt, thymol and at least one other essential oil that provides antimicrobial activity. The argument that 'Nair is silent as to stand alone film technology' is not

persuasive since the prior art of Nair *et al.* is suggestive of providing the use of essential oils, incorporated in effective amounts to clearly provide antimicrobial results in oral care compositions. The use of zinc salts is further permitted, since the instant claims utilize 'comprising' claim language and thus permits the use of additional components, besides from those recited. The instant invention desires breath-freshening, plaque and odor-reducing properties. The art is clearly indicative of and desires essential oils that permit odor-reducing, breath-freshening and antimicrobial properties. No significant, *patentable* distinction has been observed between the instant invention and the prior art, since the prior art teaches similar compositions, formulated in the same field of endeavor to treat the same problems as that desired by Applicants. Hence, the instant invention is rendered *prima facie* obvious and unpatentable over the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh *H.N.S.*

Patent Examiner

Art Unit 1615

November 01, 2004

Thurman K. Page
THURMAN K. PAGE
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